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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,862	08/06/2003	Fritz Rudert	37629-0076	8198

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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,862	RUDERT ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/6/03, 11/15/04*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/6/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed 11/15/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: (1) incorporation by reference to PCT/EP98/04836, and (2) deleting the second paragraph of page 20 to replace it with a second copy of paragraph 2.2 from pages 17-19.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 1, 16-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for filamentous bacteriophages, does not reasonably provide enablement for the full scope of "polyphages". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims, for reasons of record. Applicant has amended the claims to require the first vector to encode a filamentous phage coat protein, but does not limit the scope of particles to those of filamentous phages. This rejection could be obviated by amending claim 1, line 1, to recite "a filamentous polyphage particle".

Claims 20, 23-33, 36-41, 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites "gene II", but this designation is meaningless for the scope of the generic "polyphage," and would also be meaningless for the scope of "filamentous polyphage", since there is not a uniform gene organization or gene nomenclature that applies to all the filamentous phages. What species of phage have a "gene II"? Similarly, in claim 24, "IR1" and "IR2" are meaningless for the scope of the generic polyphage; in claim 33, the same applies to "gene VII;" in claims 36-40, "gIIIp" and "gVIIIp." In claim 33, is the intent to require an amber mutation anywhere in the vector, or an amber mutation in gene VII? In claim 46, it is not clear whether terms like "R176" refer to some specific mutation or to a particular vector. See the suggestion below for clarifying the claimed subject matter.

Claims 20, 25, 26, 40 are indefinite in reciting "mutated sequences" or "a mutant thereof", since there is no indication of the scope of alterations encompassed by the mutations. In addition, in claims 26-28 and dependent claims, it is not clear which of the claim 16 vectors is "said vector." Also, in claim 29, is the "helper phage" one of the packaged vectors?

Claims 34, 35 are indefinite in reciting "phage vectors R68 or R100" or "N18", these phage vectors do not appear to be commonly known in the art so it is not clear what these claims mean.

In claim 41, the claim requires the vector's marker element to function as a transcription transactivator of a reporter gene, or a transcription transactivator of a nutritional marker, or a transcription transactivator of an antibiotic resistance gene. Is

this really intended? The working examples have antibiotic resistance genes as selectable markers carried directly on the vectors, with no transactivation involved.

The claims would be more clear if there were some intermediate claims depending from, say, claim 16 or 17, which identify the coat protein(s) or phage origin(s) of replication as originating from phage F1, Fd, or M13 (if that is the case). Then subsequent dependent claims referring to details of specific genes, specific gene alterations, and specific sequences would further limit the scope of the coat protein(s) or origin(s) in an understandable way.

Claims 34, 35, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 34-35 require access to particular named vectors (one cannot determine whether or not one has a mutation identical to the named vector without access to the named vector). Claim 46 appears to require specific named vectors.

It is apparent that these specific biological materials are required to practice the claimed invention, because they are named in the claims. As required elements they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If they are not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the materials named in the claim.

The specification does not provide a repeatable method for obtaining the materials named in these claims, and they do not appear to be readily available

material. Deposit of the materials named in these claims would satisfy the enablement requirements of 35 U.S.C. 112. See 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Krebber et al US 5514548 and McCafferty et al WO 9201047 are cited as the closest prior art. Neither teaches or suggests copackaging two different vectors in one polyphage particle. Ilag et al WO 9732017 teaches the claimed invention, but is not available as prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

1/25/05

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1608